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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/799,521 | 03/12/2004 | Erning Xia | P03328 | 8492 |

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| EXAMINER |
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CHOI, FRANK I

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,521

Applicant(s)

XIA ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20040312.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preserving tight cell junctions, does not reasonably provide enablement for “preventing loss of tight cell junctions”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to a lens care solution containing one or more carbohydrates in an amount effective to prevent the loss of tight cell junctions.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record discloses methods and compositions as indicated below which contain carbohydrates falling within the scope of the limitation “carbohydrate” and amounts falling within the scope of the limitation “an amount effective to prevent the loss of tight cell junctions” as disclosed in the Specification. However, the prior art does not explicitly recite that said amounts would be effective in preventing loss of tight cell junctions, does not recite in the express disclosures indicated below amounts or every carbohydrate or mixture of carbohydrates which would encompass the entire scope of the claim. As such, the predictability in the art is low as to whether a given carbohydrate or mixture of carbohydrates would be effective in preventing the loss of tight cell junctions to the full extent of the scope of the claim as indicated below.

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The amount of direction or guidance present and the presence or absence of working examples:

The only working example allegedly showing prevention used only one carbohydrate, trehalose, in an amount 3% and 1.5% (Page 15, Table 1, Solutions 1,2, Pages 20, 21, Example 5). However, there was still penetration, although, to a lesser extent, after pretreatment (Page 21, Table 4).

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that the claim encompasses the use of any carbohydrate or mixture of carbohydrates in an amount only defined by the limitation that it be effective to prevent loss of tight junctions, whereas only one carbohydrate, trehalose, was tested in the amount of 3% and 1.5%. Further the claims are broad because the limitation "prevent" includes within its scope complete prevention of loss of tight cell junctions and prevention of the same without any time limit, whereas the tested did not show complete prevention or prevention for an unlimited period of time. As such, one of ordinary skill in the art would have been required to do undue experimentation in order to determine whether a given carbohydrate or mixture of carbohydrates and the amounts thereof that would be effective in preventing the loss of tight cell junctions over the full scope of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1,2,4,5,7,8,10,12,13,16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hu et al. (US 2003/0133905).

Hu et al. expressly disclose a method of dispensing an aqueous composition in the eye of a contact lens wearer while a contact lens is worn in the eye containing tromethamine, non-polymeric demulcent, chelating agent, buffering agent, surfactant and a 0.01 to 2% of cationic cellulose polymer (Claims 1, 11,13,14).

The claims require "an amount effective for preserving tight cell junctions" or "an amount effective to prevent the loss of tight cell junctions". The Specification discloses that the amount is "from approximately 0.01 to approximately 10.0 percent by weight based on the total weight of the composition). The claims require "one or more carbohydrates" which is defined by the Specification to include "oligosaccharides and polysaccharides" which are defined by the Specification to include hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, methylcellulose and carboxymethylcellulose. The prior art method uses a composition that contains 0.01 to 2% of a cationic cellulose polymer. Since the limitation "carbohydrate" includes within its scope cellulose derivatives, the cationic cellulose polymer present within the prior art method and composition falls within the scope of said limitation. Further, the cationic cellulose polymer is present in an amount which falls within the scope of the amount disclosed to by the Specification to be effective for preserving or preventing

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the loss of tight cell junctions, the prior art method and composition fall within the scope of the claimed invention.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-13, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Doi et al. (US Pat. 6,479,556).

Doi et al. expressly disclose instilling two or three drops of either an eye drop composition containing KCl and NaCl (isotonicity agents), boric acid/ sodium borate (buffer), sorbic acid, sodium edentate, 1-menthol, hydroxyethylcellulose (0.1g) (thickener), polysorbate 80, water to 100 ml or another composition containing KCl, NaCl, boric acid, sodium borate, sorbic acid, sodium edentate, hydroxyethylcellulose (0.1g), polysorbate 80, water to 100 ml in persons wearing soft contact lenses (Column 3, lines 57-60, Column 4, lines 1-3, 13, 14, 41-68, Example 1, Column 6, lines 21-49).

The claims require "an amount effective for preserving tight cell junctions" or "an amount effective to prevent the loss of tight cell junctions". The Specification discloses that the amount is "from approximately 0.01 to approximately 10.0 percent by weight based on the total weight of the composition). The claims require "one or more carbohydrates" which is defined by the Specification to include "oligosaccharides and polysaccharides" which are defined by the

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Specification to include "hydroxyethylcellulose". The prior art method uses a composition that contains 0.1g hydroxyethylcellulose in 100 ml of water, which equates to about 0.1% by weight of hydroxyethylcellulose. Since the hydroxyethylcellulose in the prior art method and composition is present in an amount which falls within the scope of the amount disclosed to by the Specification to be effective for preserving or preventing the loss of tight cell junctions, the prior art method and composition fall within the scope of the claimed invention.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Vigh (US Pat. 5,451,398).

Vigh expressly discloses soaking a contact lens for four hours with a composition containing boric acid/sodium borate (buffer), disodium ethylene diamine tetraacetate, sodium chloride (tonicity adjuster), surfactant, 0.4% hydroxyethyl cellulose (viscosity builder) and placing it directly into the eye without rinsing (Column 7, lines 24-26, 37-41, Column 10, lines 51-68, Column 2, lines 1-20).

The claims require "an amount effective for preserving tight cell junctions" or "an amount effective to prevent the loss of tight cell junctions". The Specification discloses that the amount is "from approximately 0.01 to approximately 10.0 percent by weight based on the total weight of the composition). The claims require "one or more carbohydrates" which is defined by the Specification to include "oligosaccharides and polysaccharides" which are defined by the Specification to include "hydroxyethylcellulose". The prior art method uses a composition that contains 0.4% hydroxyethylcellulose. With respect to claim 15, the only example of a medical device disclosed in the Specification is a contact lens (Specification, Paragraph 0009), as such, the soaking of the contact lens prior to placing the lens in the eye falls within the scope of the

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claim. With respect to claim 16, since the contact lens which has been soaking in the prior art composition is directly placed into the eye without rinsing, the solution which is on the lens will contact the eye, i.e the solution will contact eye tissue. Since the hydroxyethylcellulose in the prior art method and composition is present in an amount which falls within the scope of the amount disclosed to by the Specification to be effective for preserving or preventing the loss of tight cell junctions and said solution soaks a contact lens and will contact eye tissue upon placement of the unrinsed lens in the eye, the prior art method and composition fall within the scope of the claimed invention.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
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September 28, 2006


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